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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,637	11/07/2001	Yashwant M. Deo	MXI-166CP	4452
959	7590	12/07/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP.			EWOLDT, GERALD R	
28 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	
			1644	

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,637

Applicant(s)

DEO ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 4/16/04, 7/19/04, 7/29/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-26,36,37 and 40-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-35,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group V in the paper filed 04/16/04 is acknowledged.

Applicant argues that a search of the claims of Groups V and VII could be made without serious burden as said searches would be coextensive.

This argument is not found persuasive for the following reasons. While the search of products and methods of use may overlap, they are not coextensive. Whereas a product comprises only physical and structural limitations, a method of use (particularly an *in vivo* use, such as would be encompassed by the method of Group VII) comprises numerous other limitations that might include time, dosage, routes of administration, and other biological considerations. Accordingly, a showing of noncoextensive searches has been accepted by the Office as a showing a serious search and examination burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-26, 36-37, and 40-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 27-35 and 38-39 read on the elected invention and are being acted upon.

3. In view of the papers filed 7/19/04, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48 (a). The inventorship of this application has been changed by the addition of Inventors John Trembl and Michael Endres.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

4. The specification is objected to for the following informalities:

A) The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. See, for example, page 15 of the specification. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 31 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of the "conservative sequence modifications" of the molecular conjugates of Claims 31 and 34.

The specification neither defines the term nor discloses any of the modified conjugates of the claims. Given the essentially unlimited number of compositions encompassed by the claims, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

7. Claims 31 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

Given the established unpredictability of the art, the instant specification would require a significant teaching to be enabled. In particular, it is unlikely that the generic modified conjugates encompassed by the claims could function for their intended use. Note that the modified conjugates of the claims would encompass conjugates modified in the CDR binding regions of the antibody portions of the conjugates. It is well-established that even single substitutions in the CDR regions of an antibody can have a dramatic, and unpredictable, effect on antibody binding (and thus, function). See, for example, Kobayashi et al. (1999) wherein it is taught that even single conserved substitutions can have a large effect on antibody binding (see Figure 4; note the log scale). Note the breadth of the claims; the conjugates of the claims are not limited in the number of modifications/substitutions allowed. Thus, even antibodies in which all of the amino acids are changed would be encompassed by the claims.

The instant specification provides no examples of the modified conjugates of the instant claims. Accordingly, one of ordinary skill in the art must conclude that the specification fails to adequately disclose how to make and use the claimed invention. Accordingly, the invention is considered to be highly unpredictable and requiring of undue experimentation to practice as claimed.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In view of the quantity of experimentation necessary, the breadth of the claims, the lack of working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 27-30, and 38-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,922,845 (IDS) as evidenced by Geissmann et al. (2001).

The '845 patent teaches a molecular conjugate comprising an antibody that binds to dendritic cells (Fc α R) and an antigen, wherein said antigen comprises a component of a pathogen or a tumor (cancer) antigen (see column 3, lines 49-59). The reference further teaches the conjugate comprising a single chain antibody (see column 3, line 63), a pharmaceutically acceptable carrier (see column 4, line 32), and an adjuvant (see column 21, line 54). Note that the Geissmann et al. reference is not used in the rejection. The reference merely demonstrates that an antibody that binds to Fc α R (CD69) would bind dendritic cells (see Abstract).

The reference clearly anticipates the claimed invention.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 32 and 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,922,845 (IDS) in view of Tuting et al. (1998).

U.S. Patent No. 5,922,845 has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach the Pmel-17 tumor antigen.

Tuting et al. teaches that Pmel-17 is one of several well known melanoma antigen (see particularly page 1140, column 1).

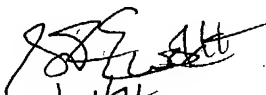
It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention to produce a molecular conjugate comprising an antibody that binds to dendritic cells and tumor antigen, as taught by the '845 patent, employing Pmel-17 as the antigen. One of ordinary skill in the art at the time the invention was made would have been motivated to employ any of the well known tumor antigens, such as Pmel-17 as taught by Tuting et al., because of their availability and previous characterization.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


10/14/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER